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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/531,676 | 04/15/2005 | Victor Sloan | PA/4-32725A | 8433 |

1095 7590 08/30/2006

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

| EXAMINER | |
|---|---|
| GRAFFEO, MICHEL | |
| **ART UNIT** | **PAPER NUMBER** |
| 1614 | |

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/531,676 | SLOAN, VICTOR | |
| | Examiner | Art Unit | |
| | Michel Graffeo | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 3-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Action*

Claims 1 and 3-9 are examined.

Applicant has amended claims 1, 3 and 7 and provided arguments for the patentability of claims 1 and 3-9 in the response filed 16 May 2006.

Applicant's arguments, see response, filed 16 May 2006, have been fully considered and are persuasive to the extent that the rejection under 35 USC §112, has been withdrawn. Any rejection not specifically stated in this Office Action has been withdrawn.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 3-9 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,869,471 to Hovancik et al.

Hovancik et al. teach a method for the treatment of rheumatoid arthritis (in current claims 1,3-9; see Abstract and col 3 lines 30-32) with 1-hydroxy-2-(imidaol-1-yl)ethane-1,1-diphosphonic acid (in current claims 6-9; see col 9 lines 52-60 wherein $R^8$

is nil, Z is a 5 membered heteroatom containing one N, m is zero, $R^1$ is H, R is $PO_3H_2$ and $R^5$ is OH) wherein treatment is administered at least 1 day of every 60 day treatment period such that the treatment periods follow one after the other (in current claims 4,5; see col 7 lines 54-60 which is interpreted to mean that two treatment periods back to back comprise 120 days and that a dose is administered at least once in each period, such that a dose can be administered on day 1 and then on day 90) and further wherein the dose administered is from 0.0005 mgP/kd (P is interpreted to mean phosphate) to 1.0mgP/Kg such that a person weighing 100kg dosed with .05mg of the bisphosphonate will be practicing the method as claimed (in current claim 9; see col 7 lines 46-53).

***Response to Arguments - 35 USC § 112***

Applicant's arguments filed 16 May 2006 have been fully considered and are persuasive.

***Response to Arguments - 35 USC § 102***

Applicant's arguments filed 16 May 2006 have been fully considered but are not persuasive. Applicant argues that the Hovancik et al. reference does not teach treatment periods which extend beyond 60 days. Examiner does not agree, see col 7 lines 50-65 copied below:

> The methods of treatment described herein are suitable for use as long-term maintenance therapies for use in treating patients with arthritis. Long term maintenance therapies generally preferably consist of sequential sixty (60)-day treatment periods, which would vary in dosages and/or types of NSAIDs and/or phosphonates, each treatment period following one after the other. As stated hereinabove, the methods of treatment described herein result in a reduction of inflammation of soft tissue in the periarticular area, but also inhibits the destruction of bone and hard tissue in the intraarticular area of the joint, thereby allowing repair of the subchondral bone.

such that treatment periods preferably consist of sequential 60 day periods.

### *Conclusion*

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

22 August 2006
MG

Ardin H. Marschel 8/27/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER